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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,821	04/19/2001	Fatih M. Uckun	12152.77USD1	2823

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[REDACTED] EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/838,821	UCKUN, FATIH M.
	Examiner Hope A. Robinson	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 April 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 April 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. The preliminary amendment filed on June 4, 2001 in Paper No. 6 has been received and entered.

***Specification***

2. The disclosure is objected to because of the following informalities:  
The specification is objected to because page 1 of the disclosure does not accurately report the continuity data as there is no indication that this application is a divisional of 09/345,815.

Correction is required.

***Information Disclosure Statement***

3. The information disclosure statement filed on July 23, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement that are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. It is noted that applicant stated that the references could be found in the parent file 09/345,815, however, not all references were found, thus a line has been drawn through all of the non-patent literature except references by Chae

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et al., Goodman et al., Karin et al., Narla et al., Riedy et al. and Rosette et al. (see the attached form).

***Claim Objection***

4. Claims 4 and 5 are objected to as being duplicative. Applicant is advised that should claim 4 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 1 is indefinite because the objective of the method is unclear as the claim recites, "a method comprising" which is open language. It is suggested that the claim be

rewritten as "a method to inhibit c-jun activation comprising...". The claim is also indefinite for the recitation of "contacting the cells with a substance that inhibits the activity of JAK-3" because it is unclear what substances have that activity or if all the substance having this activity will fully inhibit c-jun activation, as it appears that inhibition of c-jun is influenced by exposure to agents such as ultraviolet radiation (see also claim 14). The dependent claims are also included in this rejection.

***Basis For NonStatutory Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 4-5 and 9-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 of copending Application No. 09/345,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are directed to a method comprising inhibiting c-jun activation in mammalian or avian cells by contacting the cells with a substance that inhibits the activity of JAK-3 (see claim 1). The patented claims are directed to a method for inhibiting specifically c-jun activation in mammalian or avian cells comprising contacting the cells with an effective inhibiting amount of a compound of formula I (see claim 1). Note that the same formula is recited in dependent claim 9 of the instant application. Both the patented claims and the copending claims have dependent claims directed to a method performed in vitro utilizing mammalian, avian and human cells. Therefore, the disclosure in the copending application makes obvious the claimed invention in the instant application. Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions since the language in the claim is similar. Thus, the instant application claim is an obvious variation of the copending application claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, upon publication of the patented claims the rejection will no longer be provisional.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 8 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ihle et al. (WO 95/03701, February 9, 1995).

Ihle et al. teach a method to inhibit the activity of Janus family of kinase including JAK-3 (abstract, page 11 and claims 1-9 of the reference). The method taught by Ihle et al. is performed *in vitro* (page 16, see claims 4 and 5 of the instant application). In addition, Ihle et al. teach a method that uses a protein to inhibit the activity of JAK-3 (abstract and page 21, see claim 8 of the instant application). The reference further teaches that the method uses mammalian, human and avian cells (pages 15 and 32, see claims 11-13 of the instant specification. Ihle et al. also teach a therapeutic wherein the inhibitor of JAK-3 is administered (page 35, claim 14 of the instant specification). Therefore, the limitations of the claimed invention are met by the reference because Ihle et al. teach a method to inhibit the activity of JAK-3 which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2-5, 8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ihle et al. (WO 95/03701, February 9, 1995) in view of Narla et al. (Clinical Cancer Research, vol. 4, pages 1405-1414, June 1998) and Chae et al. (Cancer Research, vol. 53, pages 447-1151, February 1, 1993).

Ihle et al. teach a method to inhibit the activity of Janus family of kinase including JAK-3 (abstract, page 11 and claims 1-9 of the reference). The method taught by Ihle et al. is performed *in vitro* (page 16, see claims 4 and 5 of the instant application). In addition, Ihle et al. teach a method that uses a protein to inhibit the activity of JAK-3 (abstract and page 21, see claim 8 of the instant application). The reference further teaches that the method uses mammalian, human and avian cells (pages 15 and 32, see claims 11-13 of the instant specification). Ihle et al. also teach a therapeutic wherein the inhibitor of JAK-3 is administered (page 35, claim 14 of the instant specification). In-so-far-as Ihle et al. do not explicitly teach radiation induced activation of c-jun (see claims 2 and 3) and the substances recited in claim 10, Narla et al. disclose the quinazoline derivative 4(4'-hydroxylphenyl)-amino-6,7-dimethoxyquinazoline as an inhibitor of the EGF-R tyrosine kinase (,see page 1405, footnote 2 and 1409, col. 2, first paragraph) and Chae teach that protein tyrosine kinase activation precedes and

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perhaps mandates radiation induced activation of c-jun protooncogene expression in a human/mammalian cell (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Ihle et al. teach a method to inhibit the activity of JAK-3 which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression) and Narla et al. teaches an inhibitor of protein tyrosine kinases which in turn inhibits c-jun) and Chae teach that ionizing radiation increases the level of c-jun transcripts, thus activates c-jun. One of ordinary skill in the art would be motivated to combine the teachings of the references because it is known in the prior art that c-jun plays a role in cell proliferation. and the specification states that alterations of c-jun protooncogene expression can modulate the transcription of several growth-regulators affecting cell proliferation and differentiation (page 2). Moreover, the combined teachings of the reference indicates that c-jun expression is elevated in response to stimuli such as growth factors, cytokines and UV radiation and inhibited by quinazolines an inhibitor of JAK-3. Thus, the claimed invention is *prima facie* obvious.

### ***Conclusion***

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS *JK*

Patent Examiner

*Christopher S. Low*

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